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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/935,717	09/23/97	CATT	M 241939

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EXAMINER

PORTNER, V

ART UNIT

1641

PAPER NUMBER

8

DATE MAILED:

01/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/935,717

Applicant(s)

Catt et al

Examiner

Portner

Group Art Unit

1641

☒ Responsive to communication(s) filed on Jan 7, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 5-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 5-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1, 5-10 are pending.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated or in the alternative under 35 U.S.C. 103 as obvious over Catt et al WO 95/13531.

Catt et al disclose a reading device for test strips, wherein the test strips are claimed in combination with a test strip reader, as well as claims the combination in a form of a kit. The assay test strip may comprise the use a particulate direct label or the use of a label which is detected threw the use of electromagnetic radiation. The relationship of the test strip and the reading device is one in which the spacial relationship is interlocking to insure that a predetermined spacial relationship relative to said reading means is maintained. When the device is received into the reading device the receiving means includes an actuating means which is triggered (claim 13) by the receipt of the device and the actuating means causing the reading of the detection zone to be initiated. The test kits may comprise one or a plurality of the assay

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devices (claim 22) for the determination of an analyte. Claim 13 of Catt et al teaches a device that comprises a receiving means which upon receipt of the device into the casing results in triggering the actuating means, wherein said actuating means initiates the reading and of the detection zone of said device contained therein. The switch actuating means is taught to comprise a fixed projecting portion and a displaceable projecting portion. The casing also comprises a recessed contact portion to accommodate the fixed projecting portion of the switch actuating means. These claim limitations are suggested and taught by Catt et al (W)95/13531) on page 22, paragraph 3 to page 23-line 37. Catt et al differs from the instantly claimed invention by failing to show the detection of more than one analyte.

3. Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to determine more than one analyte with the test kits of Catt et al because Catt et al discloses that the combination test kits may comprise more than one assay device and Catt et al suggests the use of the device for the determination of more than one analyte and states that “[T]he invention can be used in the determination of any body fluid analyte, especially in the monitoring of the human ovulation cycle by the determination of one or more hormones or metabolites thereof in body fluid, such as urine for example either LH and/or estrone-3-glucuronide. (page 12, lines 4-8)” Therefore the person of ordinary skill in the art would have been motivated by the reasonable expectation of success in obtaining test kits which would determine one or more analytes in a sample of fluid because Catt et al teach that these analytes are

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important in the determination of the ovulation cycle and would aid in the identifying the time in which fertility was greatest based on the assessment of more than one hormone level.

4. ***Claim Rejections - 35 U.S.C. § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jina et al (US Pat. 5,526,120, filing date September 8, 1994).

8. Jina et al show a test strip with an asymmetrical end which insures the correct insertion for measuring for an analyte in a liquid sample. The asymmetries combine to permit a test strip to be inserted into the apparatus when it is correctly aligned and is associated with circuitry when the

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strip is fully inserted. The test strip when fully inserted closes an electrical circuit, the closing of which is monitored by the apparatus and allows the determination of an analyte (see col. 4, lines 47-67 and col. 5, lines 1-48; abstract and figures) Jina teach that the device is useful in the determination of glucose, cholesterol and alcohol in human blood (col. 5, line 35). The test strip with an asymmetrical end insures the correct insertion for measuring for an analyte in a liquid sample. The asymmetries combine to permit a test strip to be inserted into the apparatus when it is correctly aligned and is associated with circuitry when the strip is fully inserted. The test strip when fully inserted closes an electrical circuit, the closing of which is monitored by the apparatus and allows the determination of an analyte (see col. 4, lines 47-67 and col. 5, lines 1-48; abstract and figures). Jina teach that the device is useful in the determination of glucose, cholesterol and alcohol in human blood (col. 5, line 35). The reference differs from the instantly claimed invention by failing to show the formulation of the assay test strip and apparatus into kit form for the determination of one or more analytes.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to determine one or more one analytes with the device of Jina because Jina discloses that the device is useful in the determination of more than one analyte and the person of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in obtaining test kits which would be able to determine one or more analytes in a sample of fluid because Jina teach devices and means for the evaluation of analytes

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and kits are an art recognized means for the convenient distribution of assay components to the desired end user for the determination of biologically significant analytes.

9. This is a Non-Final rejection. No claims are allowed.

10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 305-7939.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1641.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

January 18, 2000


JAMES C. HOUSEL 1/18/00
SUPERVISORY PATENT EXAMINER